

EXHIBIT 1

**IN THE UNITED STATES DISTRICT COURT FOR THE
NORTHERN DISTRICT OF ILLINOIS
CHICAGO DIVISION**

JUSTIN DE LOS SANTOS,
as PARENT, NATURAL GUARDIAN
AND NEXT FRIEND OF RYAN J.
DE LOS SANTOS,

Plaintiff,

v.

ABBOTT LABORATORIES,

Defendant.

Case No.

PLAINTIFF’S COMPLAINT AND JURY DEMAND: PRODUCTS LIABILITY

INTRODUCTION

This action arises out of the injuries suffered by Plaintiff’s premature infant, who was fed Defendant’s cow’s milk-based infant formula and/or fortifier. Defendant’s products caused the injured infant to develop Necrotizing Enterocolitis (hereinafter “NEC”), a life-threatening and potentially deadly intestinal disease characterized by inflammation and injury of the gut wall barrier that may advance to necrosis and perforation of the gut. Advanced cases of NEC often lead to surgery and even death. Significantly higher rates of NEC have been found in premature or preterm babies with low birth weights who are fed cow’s milk-based formula or fortifier products. The companies who manufacture these products often intentionally mislabel and misrepresent the contents of the products both to the public at-large and to the health care community, passing off these deadly products as something similar or even superior to human breast milk. Tragically, baby Ryan J. De Los Santos, who was premature at birth, was fed these cow’s milk-based products, developed NEC, and suffered significant injuries as a result.

Plaintiff, Justin De Los Santos, as Parent, Natural Guardian, and Next Friend of Ryan J. De Los Santos, brings this cause of action against Defendant for claims arising from the direct and proximate result of Defendant's negligent, willful, and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distribution, labeling, failure to warn, and/or sale of the Defendant's cow's milk-based products (hereinafter "Cow's milk-based Formula," "Cow's milk-based Fortifier," or collectively "Cow's Milk-Based Products").

GENERAL ALLEGATIONS

Plaintiff, Justin De Los Santos, as Parent, Natural Guardian, and Next Friend of Ryan J. De Los Santos, (hereinafter "Plaintiff"), by and through the undersigned counsel, brings this Complaint against Defendant, Abbott Laboratories; and upon information and belief and based upon the investigation of counsel to date, would set forth as grounds the following:

JURISDICTION AND VENUE

1. This is an action for damages which exceeds the sum of \$75,000.00, exclusive of costs, interest, and attorneys' fees.
2. This Court has jurisdiction over this case pursuant to 28 U.S.C. §1332, as complete diversity exists between Plaintiff and the Defendant, and the matter in controversy, exclusive of interest and costs, exceeds the sum or value of \$75,000.00.
3. This Court has personal jurisdiction over Defendant because Defendant resides in this District and is incorporated under the laws of Illinois and is authorized to conduct business and does conduct business in the State of Illinois. Defendant has marketed, promoted, distributed, and/or sold its Cow's Milk-Based Products in the States of Illinois and Texas, and Defendant has sufficient minimum contacts with these states and/or sufficiently avails itself of the markets in the state through its promotion, sales, distribution, and marketing within these states to render

exercise of jurisdiction by this Court permissible.

4. Venue of this action is proper in this Court pursuant to 28 U.S.C. §§1391 (a) and (b) because a substantial part of the events or omissions giving rise to Plaintiff's claims occurred in this judicial district. Venue is also proper under 18 U.S.C. §1965 (a) because Defendant transacts substantial business in this District.

PLAINTIFF

5. Ryan J. De Los Santos was born prematurely at Driscoll Children's Hospital in Corpus Christi, Texas on October 22, 2019. Upon information and belief, Ryan J. De Los Santos developed NEC after being fed Abbott's Similac Cow's Milk-Based Products while at Driscoll Children's Hospital in Corpus Christi, Texas. At all times material hereto, Ryan J. De Los Santos was domiciled in and was a citizen of the State of Texas.

6. Plaintiff, Justin De Los Santos, the father of Ryan J. De Los Santos, was domiciled in and was a citizen of the State of Texas at all relevant times. Ryan J. De Los Santos's father brings this action against Defendant to recover for Ryan J De Los Santos's injuries, which are the direct and proximate result of consumption of Defendant's unreasonably dangerous cow's milk-based products.

DEFENDANT

Defendant, Abbott Laboratories ("Abbott") was at all times material hereto and is now a corporation duly organized, incorporated, and existing under the laws of the State of Texas with its principal place of business and headquarters in the State of Illinois and is thus a resident, citizen and domiciliary of Illinois. Abbott manufactures, designs, formulates, prepares, tests, provides instructions for, markets, labels, packages, sells, and/or places into the stream of commerce in all fifty states premature infant formula and premature infant milk fortifier under the Similac brand name, including Similac Advance Formula.

7. Defendant Abbott advertises that it provides the “#1 Formula Brand, Backed by Science” and claims to have “over 90 years of innovations” in infant formula.

FACTUAL ALLEGATIONS

The Science and Scope of the Problem

8. According to the World Health Organization (“WHO”), babies born prematurely, or “preterm,” are defined as being born alive before 37 weeks of pregnancy are completed. The WHO estimates that approximately 15 million babies are born preterm every year and that this number is rising.

9. Nutrition for preterm babies, especially those who have a very low birth weight (under 1500 grams) or extremely low birth weight (under 1000 grams) is significantly important. Since the United States ranks in the top ten countries in the world with the greatest number of preterm births, the market of infant formula and fortifiers is particularly vibrant.

10. Science and research have advanced in recent years confirming strong links between cow’s milk-based products and NEC causing and/or substantially contributing to death in preterm and severely preterm, low-weight infants, along with many other health complications and long-term risks to these babies. Additionally, advances in science have created alternative fortifiers that are derived from human milk and non-cow’s milk-based products; however, the manufacturers of the Cow’s Milk-Based Products continue to promote and sell the Cow’s Milk-Based versions.

11. As far back as 1990, a prospective, multicenter study on 926 preterm infants found that NEC was **six to ten times more** common in exclusively formula-fed babies than in those fed breast milk alone and **three times more common** than in those who received formula plus breast milk. The study also found that NEC was rare in babies born at more than 30 weeks gestation whose diet included breast milk but was **20 times more common** in those fed cow’s milk-based formula only. A. Lucas, T. Cole, *Breast Milk and Neonatal Necrotizing Enterocolitis*, LANCET,

336: 1519-1523 (1990) (emphasis added).

12. A study published in 2009 evaluated the health benefits of an exclusively human milk-based diet as compared to a diet with both human milk and cow's milk-based products in extremely premature infants. The results show that preterm babies fed an exclusively human milk-based diet were **90% less likely** to develop surgical NEC as compared to a diet that included some cow's milk-based products. S. Sullivan, *et al.*, *An Exclusively Human Milk-Based Diet Is Associated with a Lower Rate of Necrotizing Enterocolitis than a Diet of Human Milk and Bovine Milk-Based Products*, JOURNAL OF PEDIATRICS, 156: 562-7 (2010) (emphasis added).

13. In 2011, the U.S. Surgeon General published a report titled, "The Surgeon General's Call to Action to Support Breastfeeding." In it, the Surgeon General warned that "for vulnerable premature infants, **formula feeding is associated with higher rates** of necrotizing enterocolitis (NEC)." U.S. Dep't of Health & Human Serv., Off. of Surgeon Gen., "The Surgeon General's Call to Action to Support Breastfeeding," p.1, (2011) (emphasis added). This same report stated that premature infants who are not breast-fed are **138% more likely** to develop NEC. *Id.*

14. In 2012, the American Academy of Pediatrics issued a policy statement that all premature infants should be fed an exclusive human milk diet because of the risk of NEC associated with the consumption of Cow's Milk-Based Products. The Academy stated that "[t]he potent benefits of human milk are such that all preterm infants should receive human milk... If the mother's own milk is unavailable ...pasteurized donor milk should be used." *Breastfeeding and the Use of Human Milk*, PEDIATRICS, 129:e827-e841 (2012).

15. Further, a study published in 2013 showed that all 104 premature infants participating in the study receiving an exclusive human-milk based diet exceeded targeted growth standards and length and weight and head circumference gain. The authors concluded that "this study provides data showing that **infants can achieve and mostly exceed targeted growth**

standards when receiving an exclusive human milk-based diet." A. Hair, *et al.*, *Human Milk Feeding Supports Adequate Growth in Infants ≤ 1250 Grams Birthweight*, BMC RESEARCH NOTES, 6:459 (2013) (emphasis added). Thus, inadequate growth was proven to be a poor excuse for feeding Cow's Milk-Based Formula, but the practice has largely continued due to extensive and aggressive marketing campaigns conducted by infant formula companies such as the Defendant.

16. Another study published in 2013 reported the first randomized trial in extremely premature infants of exclusive human milk versus preterm cow's milk-based formula. The study found a **significantly higher rate** of surgical NEC in infants receiving the cow's milk-based preterm formula and supported the use of exclusive human milk diet to nourish extremely preterm infants in the NICU (Newborn Intensive Care Unit). E.A. Cristofalo, *et al.*, *Randomized Trial in Extremely Preterm Infants*, J PEDIATR., 163(6):1592-1595 (2013) (emphasis added).

17. In another study published in 2014, it was reported that NEC is "a devastating disease of premature infants and is associated with **significant morbidity and mortality**. While the pathogenesis of NEC remains incompletely understood, it is well established that the risk is increased by the administration of infant formula and decreased by the administration of breast milk." Misty Good, *et al.*, *Evidence Based Feeding Strategies Before and After the Development of Necrotizing Enterocolitis*, EXPERT REV. CLIN. IMMUNOL., 10(7): 875-884 (2014 July) (emphasis added). The same study found that NEC "is the **most frequent and lethal gastrointestinal disorder** affecting preterm infants and is characterized by intestinal barrier disruption leading to intestinal necrosis, multi-system organ failure and death. *Id.* The study noted that "NEC affects 7-12% of preterm infants weighing less than 1500 grams, and the frequency of disease appears to be either stable or rising in several studies. *Id.* The typical patient who develops NEC is a premature infant who displays a rapid progression from mild feeding intolerance to systemic sepsis, and **up to 30% of infants will die from this disease.**" *Id.* Advances in formula

development have made it possible to prevent necrotizing enterocolitis, and the “exclusive use of human breast milk is recommended for all preterm infants and is associated with a significant decrease in the incidence of NEC.” *Id.*

18. In another study published, in 2014 it was reported that an exclusive human milk diet, devoid of Cow’s Milk-Based Products, was associated with “lower mortality and morbidity” in extremely preterm infants without compromising growth and should be considered as an approach to nutritional care of these infants. Steven Abrams, *et al.*, *Greater Mortality and Morbidity in Extremely Preterm Infants Fed a Diet Containing Cow Milk Protein Products*, BREASTFEEDING MEDICINE, 9(6):281-286 (2014).

19. In 2016, a large study supported previous findings that an exclusive human milk diet in extreme preterm infants significantly decreased the incidence of both medical and surgical NEC. This was the first study to compare rates of NEC after a feeding protocol implementation at multiple institutions and years of follow-up using an exclusive human milk diet. The authors concluded that the use of an **exclusive human milk diet is associated with “significant benefits”** for extremely preterm infants and while evaluating the benefits of using an exclusive human milk-based protocol, “it appears that there were **no feeding-related adverse outcomes**.” Hair, *et al.*, *Beyond Necrotizing Enterocolitis Prevention: Improving Outcomes with an Exclusive Human Milk Based Diet*, BREASTFEEDING MEDICINE, 11-2 (2016) (emphasis added).

20. A publication by the American Society for Nutrition, in 2017, noted that human milk has “been acknowledged as the best source of nutrition for preterm infants and those at risk for NEC.” The study compared the results from two randomized clinical trials on preterm infants with severely low weight (between 500 and 1250 grams at birth) and compared the effect of cow’s milk-based preterm infant formula to human milk as to the rate of NEC. Both trials found that an **exclusive human milk diet resulted in a much lower incidence of NEC**. While the study noted

that cow's milk-based preterm formulas provided consistent calories and were less expensive than human milk-based products, the **cow's milk-based products significantly increase the risk of NEC and death**. The study also noted the **"exponential" health care costs** associated with NEC and noted data from the U.S. from 2011-2012 that showed that the cost of NEC is \$180,000 to \$198,000 per infant and nearly doubles to \$313,000 per infant for surgically treated NEC. Further, NEC survivors accrue substantially higher outpatient costs. Jocelyn Shulhan, *et al.*, *Current Knowledge of Necrotizing Enterocolitis in Preterm Infants and the Impact of Different Types of Enteral Nutrition Products*, ASN ADV. NUTR., 8(1):80-91 (2017) (emphasis added).

21. The WHO and United Nation's International Children's Emergency Fund (UNICEF) held a meeting more than two decades ago to address concerns over the marketing of breast-milk substitutes. The WHO Director concluded the meeting with the following statement, **"In my opinion, the campaign against bottle-feed advertising is unbelievably more important than the fight against smoking advertisement."** Jules Law, *The Politics of Breastfeeding: Assessing Risk, Dividing Labor*, JSTOR SIGNS, vol. 25, no. 2: 407-50 (2000) (emphasis added).

22. Recognizing the abuse and dangers of the marketing of infant formula, in 1981, the World Health Assembly ("WHA"), the decision-making body of the world's Member States, developed the International Code of Marketing of Breast-milk Substitutes ("the Code"), which required companies to acknowledge the superiority of breast milk and outlawed any advertising or promotion of breast milk substitutes to the general public. Pursuant to Article 5.1 of the Code, advertising of breast-milk substitutes is specifically prohibited: **"There should be no advertising or other form of promotion to the general public** [of breast milk substitutes]." (Emphasis added). In Article 5.2, the Code states that "manufacturers and distributors should not provide, **directly or indirectly**, to pregnant women, mothers or members of their families, samples of products within the scope of this Code." In addition, the Code expressly prohibits, "point-of-sale advertising,

giving of samples, or any other promotion device to induce sales directly to the consumer at the retail level, such as special displays, discount coupons, premiums, special sales...” *See* Int’l Code of Marketing of Breast-Milk Substitutes, May 21, 1981, WHA 34/1981/REC/2, Art.5.3.

23. The World Health Organization’s 2018 Status Report on this issue noted that “despite ample evidence of the benefits of exclusive and continued breastfeeding for children, women, and society, far too few children are breastfed as recommended.” The Status Report states that “**a major factor undermining efforts to improve breastfeeding rates is continued and aggressive marketing of breast-milk substitutes**,” noting that in 2014, the global sales of breast-milk substitutes amounted to **US \$44.8 billion** and “is expected to rise to **US \$70.6 billion** by 2019.” *Marketing of Breast-milk Substitutes: Nat’l Implementation of the Int’l Code, Status Report 2018*. Geneva: World Health Org., 2018, p.21 (emphasis added).

24. Recognizing a shift in the medical community towards an exclusive human milk-based diet for preterm infants, the Defendant began heavily promoting “human milk fortifiers,” a name which misleadingly suggests that the product is derived from human milk, instead of being derived from Cow’s Milk.

25. The Defendant has designed a systematic, powerful, and misleading marketing campaign to persuade physicians and parents to believe that: (1) Cow’s Milk-based formula and fortifiers are safe; (2) Cow’s Milk-Based Products are equal, or even superior, substitutes to breastmilk; and (3) physicians consider their Cow’s Milk-Based Products a first choice. Similarly, Defendant markets its products for preterm infants as necessary for growth, and perfectly safe for preterm infants, despite knowing of the extreme risks posed by Cow’s Milk-Based Products and failing to warn of the deadly disease of NEC and risk of death.

26. Thus, despite the existence of alternative and safe human milk-based fortifiers, Defendant continues to market and/or sell the Cow’s Milk-Based Products under the guise of being

a safe product for their newborns and despite knowing the significant health risk posed by ingesting these products, especially to preterm, low weight infants.

The Inadequate Warnings

27. Defendant promotes the use of its preterm infant Cow's Milk-Based Products to parents, physicians, hospitals, and medical providers as safe products that are specifically needed by preterm infants for adequate growth.

28. Despite the knowledge of the significant health risks posed to preterm infants ingesting the Cow's Milk-Based Products, including the significant risk of NEC and death, Defendant did not warn parents or medical providers of the risk of NEC in preterm infants, nor did Defendant provide any instructions or guidance on how to properly use its Cow's Milk-Based Products so as to lower the risk or avoid NEC or death.

29. In fact, the Defendant does not provide any warning in its labeling, websites, or marketing that discusses the risk of NEC and death with use of its Cow's Milk-Based Products with preterm infants.

30. Thus, Defendant does not warn the users, the parents, or the medical providers and staff that these Cow's Milk-Based Products can cause NEC or death, nor do they provide any guidance on how to avoid or reduce the risks of NEC or death while using its products.

Ryan J. De Los Santos and the Dangerous, Defective Products

31. Ryan J. De Los Santos was born prematurely at Driscoll Children's Hospital in Corpus Christi, Texas on October 19, 2019. Ryan J. De los Santos was born preterm at 37 weeks.

32. On October 22, 2019, Ryan J. De Los Santos was admitted to the Neonatal ICU.

33. On October 28, 2019, Ryan J. De Los Santos started trophic feeds with Similar Advance formula.

34. From October 28, 2019 to November 8, 2019, Ryan J. De Los Santos received

Similar Advance formula.

35. On November 8, 2019, Ryan J. De Los Santos was worked up for a bloody stool.

36. On November 8, 2019, an exploratory laparotomy was conducted on Ryan J. De Los Santos. Necrotizing enterocolitis (NEC) with substantial pneumatosis and abdominal free air was noted.

37. On November 22, 2019, Ryan J. De Los Santos completed a 14-day regime of antibiotics for NEC.

38. On November 25-26, 2019, Ryan J. De Los Santos received abdominal x-rays concerning residual pneumatosis and NEC follow-up.

39. On December 24, 2019, Ryan J. De Los Santos was discharged from Driscoll Children's Hospital.

40. At the time he was diagnosed with and treated for NEC, Ryan J. De Los Santos's parents were unaware of the fact that the Defendant's Cow's Milk-Based Products he was fed caused or substantially contributed to his development of NEC and resulting injuries.

COUNT I: STRICT LIABILITY AS TO DEFENDANT ABBOTT'S DESIGN

41. Plaintiffs incorporate by reference each of the preceding paragraphs as if fully set forth herein.

42. At all times material to this action, Defendant Abbott was engaged in the sale, and/or marketing and/or design, and/or manufacture, and/or distribution of Cow's Milk-Based Products, which are defectively designed and/or unreasonably dangerous to consumers.

43. Defendant Abbott, as a manufacturer, has a duty to hold the knowledge and skill of an expert and is obliged to keep abreast of any scientific discoveries and are presumed to know the result of all such advances.

44. At all times material to this action, the Cow's Milk-Based Products manufactured,

distributed and/or sold by Defendant Abbott, were in a defective and/or unreasonably dangerous condition at the time the products were placed in the stream of commerce for nutritional use for preterm infants.

45. Defendant Abbott specifically marketed and created its Cow's Milk-Based Products for use as nutrition and nutritional supplements for preterm infants.

46. Defendant Abbott's Cow's Milk-Based Products are expected to and do reach the user without substantial change affecting that defective and/or unreasonably dangerous condition.

47. Prior to Plaintiff's birth, Defendant Abbott was aware or should have been aware that its Cow's Milk-Based Products were not safe for use, as they were used, as nutrition or nutritional support in preterm infants, yet they took no steps to prevent the use of these products in such situations.

48. Defendant Abbott knew or should have known that the use of its Cow's Milk-Based Products with preterm infants was unreasonably dangerous in that its Cow's Milk-Based Products significantly increased the risk of NEC.

49. Furthermore, scientific data and well-researched studies have concluded that the Cow's Milk-Based Products of the Defendant carried unreasonable risks of NEC and death, which far outweighed the products' benefits for preterm infants.

50. Despite the foregoing, the Defendant continued to sell and market its defective and/or unreasonably dangerous products to preterm infants.

51. The products were defectively manufactured and/or designed and/or unreasonably dangerous, including, but not limited to the following particulars:

- a. The products did not perform as safely as an ordinary consumer would expect when used in the intended or reasonably foreseeable manner, such that the use of Cow's Milk-Based Products as nutrition or nutritional supplements in preterm infants

significantly increased the risk of NEC;

- b. The products contained hidden and dangerous design defects and were not reasonably safe as intended to be used, subjecting preterm infants, to risks of serious bodily injury;
- c. The products failed to meet legitimate, commonly held, minimum safety expectations of that product when used in an intended or reasonably foreseeable manner;
- d. Defendant failed to utilize economical and technically available safer design alternatives for preterm infant formula and fortifiers;
- e. The products were manifestly unreasonable in that the risk of harm so clearly exceeded the products' utility that a reasonable consumer, informed of those risks and utility, would not purchase the product;
- f. Defendant failed to adopt an adequate or sufficient quality control program; and/or
- g. Defendant failed to inspect or test its products with sufficient care.

52. As a direct and proximate cause of the Cow's Milk-Based Product's unreasonable dangerous condition, Plaintiff suffered serious bodily injury.

WHEREFORE, Plaintiff, by and through undersigned counsel, demands judgment against Defendant Abbott Laboratories for all applicable damages, costs of this action, post-judgment interest, and trial by jury.

COUNT II: NEGLIGENCE AS TO DEFENDANT ABBOTT

53. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

54. Defendant Abbott, as the manufacturer and/or seller of Cow's Milk-Based

Products, owed a duty to the consuming public in general, and Plaintiff in particular, to exercise reasonable care to design, test, manufacture, inspect, and distribute a product free of unreasonable risk of harm to users and patients, when said product is used in its intended manner.

55. Defendant Abbott, as a manufacturer, has a duty to hold the knowledge and skill of an expert and is obliged to keep abreast of any scientific discoveries and are presumed to know the result of all such advances.

56. Defendant Abbott, directly or indirectly, negligently, and/or defectively made, created, manufactured, designed, assembled, tested, marketed and/or sold the subject Cow's Milk-Based Products.

57. Defendant breached the duty owed to Plaintiff and acted negligently in its actions, including, but not limited to, the following:

- a. Designed the products such that there are latent and not obvious dangers for consumers and patients while the products are being used in a foreseeable and intended manner;
- b. The products contained hidden and dangerous design defects and were not reasonably safe as intended to be used, subjecting preterm infants to risks of serious bodily injury and death in that the products' design and/or manufacture amounted to and/or resulted in a defect failure mode of the products;
- c. Failing to collect data to determine if its products were safe for preterm infants;
- d. Failing to collect data to determine when and how its products could be used safely;
- e. Failing to utilize the significant peer reviewed research to develop instructions;
- f. Failing to develop evidence-based guidelines or instructions to decrease the risk of its products causing NEC and death;
- g. Failing to provide evidence-based guidelines or instructions to decrease the risk of

- its products causing NEC and death;
- h. Failing to stop or deter its products from being fed to preterm infants like Baby Mason;
- i. Failing to provide evidence-based instructions or guidance on when or how a preterm infant should be transitioned to the products;
- j. Failing to update its warnings and/or instructions based upon currently available data, research, and studies;
- k. Failing to take reasonable steps to prevent preterm infants from developing NEC and/or death
- l. Failing to take reasonable precautions to prevent preterm infants from developing NEC and/or death
- m. Improperly creating agreements with hospitals whereby its products would be over utilized to the detriment of the preterm infants; and/or
- n. Improperly promoting continued use of its product in hospitals despite knowing of the great harm it was causing; and/or
- o. Failing to develop comprehensive mitigation strategies to reduce the risk of NEC and/or death in its products; and/or
- p. Intentionally promoting a culture of silence whereby the harmful effects of its products were never being communicated to the parents or the public; and/or
- q. Failing to insert a warning or instruction to healthcare professionals in the NICU that parents should be provided information necessary to make an informed choice about whether to allow their babies to be fed cow's milk-based products; and/or
- r. Failing to continuously and vigorously study its cow's milk-based products in order to avoid NEC and death in premature infants;

- s. Failing to utilize economical and technically available safer manufacturing and/or design alternatives for the preterm infant formula and fortifier;
- t. Failing to adopt an adequate or sufficient quality control program; and/or
- u. Failing to inspect or test their products with sufficient care.

58. Defendant Abbott knew or should have known that its products were to be used as nutrition and nutritional supplements with preterm infants.

59. Defendant Abbott knew or should have known that the use of its Cow's Milk-Based Products with preterm infants was unreasonably dangerous in that its Cow's Milk-Based Products significantly increased the risk of NEC.

60. Furthermore, scientific data and well researched studies have concluded that the Cow's Milk-Based Products of the Defendant carried unreasonable risks of NEC and death, which far outweighed the products' benefits for extremely premature infants.

61. As a direct and proximate result of the negligence of Defendant Abbott, Plaintiff suffered serious bodily injury.

WHEREFORE, Plaintiff, by and through undersigned counsel, demands judgment against Defendant Abbott Laboratories for all applicable damages, costs of this action, post-judgment interest, and trial by jury.

COUNT III: FAILURE TO WARN AS TO DEFENDANT ABBOTT

62. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

63. Defendant Abbott, as the manufacturer and/or seller of Cow's Milk-Based Products, owed a duty to the consuming public in general, and Plaintiff in particular, to properly warn and provide adequate warnings or instructions about the dangers and risks associated with the use of Cow's Milk-Based Products with preterm infants, specifically including but not limited

to the risk of NEC.

64. Defendant Abbott, as the manufacturer and/or seller of Cow's Milk-Based Products, was unreasonable in relying upon any intermediary, including physicians, other health care providers or health care staff, to fully warn the end user of the hidden dangers and risks in its Cow's Milk-Based Products, as the magnitude of the risk involved is using Defendant's Cow's Milk-Based Products with preterm infants is significant and involves the real danger of serious bodily injury and death.

65. Defendant Abbott, as the manufacturer and/or seller of Cow's Milk Products, owed a duty to fully warn and instruct any intermediary, including physicians, other health care providers or health care staff, of the significant dangers in its Cow's Milk-Based Products.

66. Defendant owed a duty to provide warnings and instructions on its Cow's Milk-Based Products marketed and/or sold for use with preterm infants that adequately communicated information on the dangers and safe use of the product to health care providers and staff using these products in a Newborn Intensive Care Unit ("NICU"), taking into account the characteristics of, and the ordinary knowledge common to, such prescribing health care providers and administering health care staff and to specifically warn of the risks and danger associated with the use of Cow's Milk-Based Products with preterm infants, specifically including but not limited to the risk of NEC.

67. Rather than provide adequate warnings, Defendant Abbott developed relationships which included incentives and financial gain to health care providers and facilities for using its Cow's Milk-Based Products within the NICU, such that health care providers and facilities had an incentive to withhold any instructions and/or warnings from the end user.

68. In addition and/or in the alternative, if healthcare providers and health care staff had been properly instructed and warned of the risks associated with the use of Cow's Milk-Based

Products with preterm infants, they would have not used such a dangerous product.

69. Defendant Abbott, as a manufacturer, has a duty to hold the knowledge and skill of an expert and is obliged to keep abreast of any scientific discoveries and are presumed to know the result of all such advances.

70. Defendant Abbott, through their own testing and studies, consultants and experts, and/or knowledge of the scientific literature, as more specifically set forth in **The Science and Scope of the Problem** Section knew of the significant risk of NEC with preterm infants.

71. Defendant Abbott, through its knowledge, review, and survey of the scientific literature, as detailed in **The Science and Scope of the Problem** Section, knew that the use of Cow's Milk-Based Products with preterm infants could cause severe injury, including but not limited to NEC and death.

72. Defendant Abbott breached the foregoing duties and failed to provide proper warnings and/or instructions of its Cow's Milk-Based Products, including but not limited to the following acts:

- a. Providing **no warnings** regarding the risk of NEC;
- b. Providing inadequate labeling that failed to warn of the risks of use of Cow's Milk-Based Products with preterm infants, including but not limited to NEC;
- c. Failed to provide proper instructions or guidelines or studies, or data on when and how to feed its products to preterm infants in order to decrease the risk of NEC;
- d. Failed to insert a warning or instruction that parents needed to be provided an informed choice between the safety of human milk versus the dangers of the defendant's Cow's Milk Product;
- e. Failed to provide instructions to consumers and health care providers that the Defendant's products carried a significant risk that its Cow's Milk-Based Products

could cause their baby to develop NEC;

- f. The warnings and instructions are severely inadequate, vague, confusing, and provide a false sense of security in that they warn and instruct on certain conditions, but do not warn on the use of Cow's Milk-Based Products significantly increasing the risk of NEC and fail to provide any details on how to avoid such harm;
- g. Failed to contain a large and prominent "black box" type warning that its Cow's Milk-Based Products are known to significantly increase the risk of NEC when compared to Human Milk in preterm infants;
- h. Failed to provide well researched and well-established studies that linked its Cow's Milk-Based Products to NEC in preterm infants;
- i. Failed to cite to or utilize current up-to-date medical data on the proper and safe use of its products;
- j. Failed to otherwise warn physicians, and healthcare providers of the extreme risks associated with feeding preterm infants Cow's Milk-Based Products;
- k. Failed to send out "Dear Dr." letters warning of the risks of NEC and death and the current scientific research and data to better guide the hospitals and physicians to better care for the extremely preterm infants;
- l. Failed to advise physicians and healthcare providers that Cow's Milk-Based Products are not necessary to achieve growth and nutritional targets for preterm infants; and/or
- m. Failed to contain sufficient instructions and warnings on the Cow's Milk-Based Products such that health care providers and health care staff were not properly warned of the dangers of NEC with use of Cow's Milk-Based Products and preterm infants.

73. As a direct and proximate result of Defendant Abbott's failure to warn, Plaintiff suffered serious bodily injury.

WHEREFORE, Plaintiff, by and through undersigned counsel, demands judgment against Defendant Abbott Laboratories for all applicable damages, costs of this action, post-judgment interest, and trial by jury.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment as follows:

1. For compensatory damages in an amount to be proven at trial;
2. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, loss of consortium, and other non-economic losses sustained as a result of Defendant's conduct;
3. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;
4. For interest as permitted by law;
5. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and
6. For such other and further relief as the Court deems proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby requests a trial by jury on all issues triable by jury.

Dated: March 2, 2022

Respectfully submitted,

/s/ Timothy J. Becker

Timothy J. Becker (#256663)

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Attorneys for Plaintiff

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)

I. (a) PLAINTIFFS

Justin De Los Santos, as Parent, Natural Guardian and
Next Friend of Ryan J. De Los Santos

(b) County of Residence of First Listed Plaintiff Nueces County, TX
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys (Firm Name, Address, and Telephone Number)

Timothy J. Becker, Stacy H. Hauer, Alexandra W.
Robertson, Johnson Becker, PLLC, 444 Cedar St.,
#1800, St. Paul, MN 55101, 612-436-1800

DEFENDANTS

Abbott Laboratories

County of Residence of First Listed Defendant Lake County, IL
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF
THE TRACT OF LAND INVOLVED.

Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff ☐ 3 Federal Question (U.S. Government Not a Party)
- ☐ 2 U.S. Government Defendant ☒ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)

- | | PTF | DEF | | PTF | DEF |
|---|---------------------------------------|----------------------------|---|----------------------------|---------------------------------------|
| Citizen of This State | <input type="checkbox"/> 1 | <input type="checkbox"/> 1 | Incorporated or Principal Place of Business In This State | <input type="checkbox"/> 4 | <input checked="" type="checkbox"/> 4 |
| Citizen of Another State | <input checked="" type="checkbox"/> 2 | <input type="checkbox"/> 2 | Incorporated and Principal Place of Business In Another State | <input type="checkbox"/> 5 | <input type="checkbox"/> 5 |
| Citizen or Subject of a Foreign Country | <input type="checkbox"/> 3 | <input type="checkbox"/> 3 | Foreign Nation | <input type="checkbox"/> 6 | <input type="checkbox"/> 6 |

IV. NATURE OF SUIT (Place an "X" in One Box Only)

Click here for: [Nature of Suit Code Descriptions.](#)

CONTRACT	TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
<input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excludes Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	PERSONAL INJURY <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury <input type="checkbox"/> 362 Personal Injury - Medical Malpractice PERSONAL INJURY <input checked="" type="checkbox"/> 365 Personal Injury - Product Liability <input type="checkbox"/> 367 Health Care/Pharmaceutical Personal Injury Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability PERSONAL PROPERTY <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability	<input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 690 Other LABOR <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Management Relations <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 751 Family and Medical Leave Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Employee Retirement Income Security Act IMMIGRATION <input type="checkbox"/> 462 Naturalization Application <input type="checkbox"/> 465 Other Immigration Actions	<input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 INTELLECTUAL PROPERTY RIGHTS <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 835 Patent - Abbreviated New Drug Application <input type="checkbox"/> 840 Trademark <input type="checkbox"/> 880 Defend Trade Secrets Act of 2016 SOCIAL SECURITY <input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g)) FEDERAL TAX SUITS <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS—Third Party 26 USC 7609	<input type="checkbox"/> 375 False Claims Act <input type="checkbox"/> 376 Qui Tam (31 USC 3729(a)) <input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit (15 USC 1681 or 1692) <input type="checkbox"/> 485 Telephone Consumer Protection Act <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 896 Arbitration <input type="checkbox"/> 899 Administrative Procedure Act/Review or Appeal of Agency Decision <input type="checkbox"/> 950 Constitutionality of State Statutes
REAL PROPERTY <input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property	CIVIL RIGHTS <input type="checkbox"/> 440 Other Civil Rights <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 445 Amer. w/Disabilities - Employment <input type="checkbox"/> 446 Amer. w/Disabilities - Other <input type="checkbox"/> 448 Education PRISONER PETITIONS Habeas Corpus: <input type="checkbox"/> 463 Alien Detainee <input type="checkbox"/> 510 Motions to Vacate Sentence <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty Other: <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition <input type="checkbox"/> 560 Civil Detainee - Conditions of Confinement			

V. ORIGIN (Place an "X" in One Box Only)

- ☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District (specify) ☐ 6 Multidistrict Litigation - Transfer ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):
28 USC 1332 Diversity of Citizenship

Brief description of cause:
Personal Injury - Product Liability

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P.

DEMAND \$
75000

CHECK YES only if demanded in complaint:

JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions):

JUDGE Hon. Rebecca R. Pallmeyer

DOCKET NUMBER 1:22-cv-00197

DATE

3/2/2022

SIGNATURE OF ATTORNEY OF RECORD

/s/ Timothy J. Becker

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

- I.(a) Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.
 - (b) County of Residence.** For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)
 - (c) Attorneys.** Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".
- II. Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
- United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here. United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
- Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
- Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; **NOTE: federal question actions take precedence over diversity cases.**)
- III. Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.
- IV. Nature of Suit.** Place an "X" in the appropriate box. If there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: [Nature of Suit Code Descriptions](#).
- V. Origin.** Place an "X" in one of the seven boxes.
- Original Proceedings. (1) Cases which originate in the United States district courts.
- Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441.
- Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
- Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
- Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
- Multidistrict Litigation – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.
- Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket.
- PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7.** Origin Code 7 was used for historical records and is no longer relevant due to changes in statute.
- VI. Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service.
- VII. Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
- Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
- Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.
- VIII. Related Cases.** This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.